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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,111	05/14/2001	Louis Schofield	017227/0172	1473

7590 05/23/2003

Foley & Lardner
3000 K Street NW Suite 500
PO Box 25696
Washington, DC 20007-8696

EXAMINER
MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
1645	12

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,111	SCHOFIELD, LOUIS	
	Examin r	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *1-37 and 40-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37 and 40-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 5 sheets
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group III, claims 38 and 39, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that Group I does not lack novelty in view of Richardson et al and that restriction between Groups I and III is improper. Applicant asserts that the same general inventive concept of using a "molecule capable of inducing an immune response directed to a micro-organism GPI inositolglycan domain" but not "to a lipidic domain of a GPI" (claim 39) informs a vaccine containing such a molecule, per Group III, and immune response-inducing methodology that employs the same sort of molecule. This is not found persuasive. It is noted that claim 1 recites that the composition comprise a "molecule", which molecule could be an antibody to GPI, a peptide, an antigen or the GPI itself. The recitation of "molecule is overly broad. Further, Richardson et al discloses a glycoprotein from a micro-organism (from the gut cells of cattle tick), the recombinant protein anchored to GPI membrane anchor and that this protein showed strong protective activity against ticks in cattle vaccinated with this protein (abstract). Figure 1 of Richardson et al discloses antibody against GPI was developed (see lane 3). With regard to Groups I and III, it is noted that Group I comprises a first claimed product and a first claimed method of using that product, which Applicant is entitled. Additional product, methods of preparing and methods of use have been individually grouped as single inventions, see Groups II-VII of the Restriction Requirement mailed September 4, 2002.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-37 and 40-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

3. Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of "capable"; it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Does the molecule induce an immune response or not? The claims are vague and indefinite in the recitation of "substantially incapable", what are the metes and bounds? The claims are vague and indefinite because it contains the use of an alternative expression ("and/or") wherein the limitation covers two different elements, i.e. "carriers" is not the same as "diluents". See MPEP 706.03(d), paragraph 5. The claims are vague and indefinite in the recitation of "a micro-organism GPI inositolglycan"; what does Applicant intend? The claims are vague and indefinite in the recitation of "a molecule"; what does Applicant intend? Is the term molecule intended to mean any antibody, peptide, protein, antigen, antibody to the GPI, a modified GPI molecule, or the GPI itself? The recitation of "a molecule" is overly broad. Claim 39 is vague and indefinite in the recitation of "modified GPI molecule or derivative or equivalent thereof"; what does Applicant intend? Claim 39 is vague and indefinite in the recitation of "insufficient"; what are the metes and bounds of

insufficient? How much of the lipidic domain can still remain yet an immune response be achieved?

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 38 is rejected under 35 U.S.C. 102(b) as being anticipated by Tachado et al 1996 (Journal of Immunology, 156:1897-1907) or Tachado et al 1994 (BBRC, 205/2:984-991).

Claim 38 is directed to a composition comprising a molecule capable of inducing an immune response directed to a micro-organism GPI inositolglycan domain but substantially incapable of inducing an immune response directed to a lipidic domain of a GPI and a pharmaceutically acceptable carrier or diluent. It is noted that molecule is being interpreted broadly to mean either a protein, peptide antigen, antibody or the GPI itself. Further, the specification has not defined diluents.

Tachado et al 1996 discloses a GPI in a buffer of choice (p. 1898). Tachado et al 1996 discloses anti-GPI monoclonal antibodies in PBS (a diluent or pharmaceutically acceptable carrier) (p. 1899).

Tachado et al 1994 discloses a GPI from a micro-organism as well as a mAb raised against a malarial GPI (abstract; p. 989).

It is noted that the recitation of "vaccine" is viewed as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Since the Patent Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Tachado et al 1997 (PNAS, USA, 94:4022-4027), Schofield et al 1996 (Journal of Immunology, 156:1886-1896) or Richardson et al 1993 (Insect Molecular Biology, 1/3:139-147).

Tachado et al 1997 discloses GPI anchored surface proteins and mAb to the GPI (abstract). The prior art discloses a diluent (water). Tachado et al 1997 discloses derivatives or precursors of the GPI (materials and methods).

Schofield et al 1996 discloses a GPI of malaria parasite origin and in PBS, water or buffer of choice (abstract; p. 1887). Schofield et al 1996 discloses mAb to malarial GPI (p. 1887).

Richardson et al 1993 discloses a glycoprotein from a micro-organism (from the gut cells of cattle tick), the recombinant protein anchored to GPI membrane anchor and that this protein showed strong protective activity against ticks in cattle vaccinated with this protein (abstract). Figure 1 of Richardson et al discloses antibody against GPI was developed (see lane 3). The recombinant protein in viewed as a derivative of the GPI. The protein was used in a vaccination composition comprising an adjuvant (i.e. pharmaceutically acceptable carrier) (p. 146).

It is noted that the recitation of "vaccine" is viewed as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Since the Patent Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
May 15, 2003